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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/332,803	06/14/99	VOGELS	R 4075US

HM12/0925

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EXAMINER	
GUZO,D	
ART UNIT	**PAPER NUMBER**
1636	16

DATE MAILED: 09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/332,803	Applicant(s) VOGELS, RONALD	
	Examiner David Guzo	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/2/01* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,6,8,10,13,14,16,17,23-32,53,60,62,66,69,70,72-78* is/are pending in the application.

4a) Of the above claim(s) *23-32,53 and 74-78* is/are withdrawn from consideration.

5)☐ Claim(s) *16 and 17* is/are allowed.

6)☒ Claim(s) *3,6,8,10,13,14,36,60,62,66,69,70,72 and 73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 23-32, 53 and 74-78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

The Sequence Listing filed 7/2/01 is acceptable and has been entered.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 6, 14, 62 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Berkner or Stratford-Perricaudet et al.

Both applicants and Berkner (Curr. Top. Micro. Immuno., 1992, Vol. 158, see whole article, particularly pp. 47-50) as well as Stratford-Perricaudet et al. (Human gene Transfer, 1991, Vol. 219, pp. 51-61, see whole article, particularly pp. 52 and 55) recite a method for generating adenoviral vectors comprising the same method steps, i.e. welding together two nucleic acid molecules (by a single homologous recombination event) wherein each nucleic acid is incapable of replicating in mammalian cells, each comprises an ITR, overlapping sequences, etc. and wherein the resultant vector comprises two ITRs, an encapsidation sequence, a gene of interest, optionally the E2

and/or E4 regions, etc. Therefore, Berkner and Stratford-Perricaudet et al. both teach the claimed invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berkner or Stratford-Perricaudet et al. either in view of Fallaux et al.

Applicants recite a method of generating an adenoviral vector comprising combining two different nucleic acid sequences in PER.C6 cells.

Berkner and Stratford-Perricaudet et al. are recited as in the above 35 USC 102(e) rejection of claims 3, 6, 14, 62 and 70. Neither Berkner nor Stratford-Perricaudet et al. recite use of PER.C6 cells for generation of adenoviral vectors.

Fallaux et al. (U.S. Patent 5,994,128, see whole article, particularly column 16 and Table II recites the generation of PER.C6 cells and the desirability of using said cells for generating adenoviral vectors.

The ordinary skilled artisan, seeking to choose a suitable cell for generating recombinant adenoviral vectors of the type disclosed by Berkner or Stratford-Perricaudet et al. would have been motivated to choose PER.C6 cells because these cells were known in the art (See Fallaux et al.) to be especially suitable for producing adenoviral vectors. It would have been obvious for the ordinary skilled artisan to do this because Fallaux et al. teaches that PER.C6 cells are especially suitable for producing recombinant adenoviral vectors. Given the teachings of the cited references and the level of skill of the ordinary skilled artisan at the time the invention was made, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 13 and 69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have responded to this rejection by submitting a Deposit Declaration. However, the Declaration is deficient because the deposit was made after the effective filing date of the application but the Declaration does not comply with 37 CFR 1.804(b). Specifically, the Declaration did not include a statement that the biological material which is deposited is the biological material specifically identified in the application as filed. The rejection will be maintained until a suitable Deposit Declaration is received.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 3, 8, 10, 14, 60, 62, 66, 69, 70, 72 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 62, 66, 69, 70, 72 and 73 are vague with respect to the term "essentially only one" homologous recombination event. Applicants traverse this rejection by asserting that the term is defined in the specification.

Applicant's arguments filed 7/2/01 have been fully considered but they are not persuasive. The specification does not delineate the metes and bounds of the claim language. For example, the specification does not exclude the occurrence of a second or third, etc. homologous recombination event.

Claims 3, 10, 73 are vague in the recitation of the phrase "...derivatives and/or analogues thereof..." . This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicants have responded to this rejection by asserting that the instant specification provides explanations for this language. Applicants indicate that the specification clearly indicates the term "derivatives and/or analogues thereof" encompasses fragments, derivatives and analogues that retain the functions of the pertinent nucleic acid sequence.

Applicants arguments have been considered but are not deemed to be persuasive. The specification does not define the metes and bounds of the term "derivatives and/or analogues thereof" with regard to adenoviral sequences such as ITRs, adenoviral genes such as E3, etc. It is unclear how closely related to the original sequence a "derivative" or "analogue" can be, i.e. can an analogue of an adenoviral ITR be derived from another non-adenoviral virus.

Claim 14 is vague in the recitation, in line 6, of the term "said nucleic acid" because the claim recites two nucleic acid molecules and it is unclear which nucleic acid molecule is being referred to by the term "said nucleic acid".

Claims 8, 60 and 73 are vague in that these claims depend from cancelled claims.

Any rejections not repeated in this Office Action are withdrawn.

Claims 16-17 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-

1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Robert Schwartzman, can be reached on (703) 308-7307. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding or relating to attachments to this Office Action should be directed to Patent Analyst Zeta Adams whose telephone number is (703) 305-3291.

David Guzo
September 22, 2001

DAVID GUZO
PRIMARY EXAMINER